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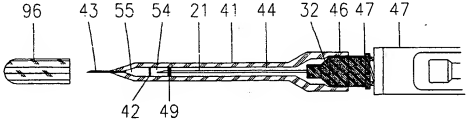

(57) Abstract

A needle for use in injecting minute quantities of anaesthetic liquid subcutaneously, comprising a fine short needle (33) having a relatively thin diameter. The fine short needle (33) is mounted from a sheath (31) in flow relationship therewith. In one embodiment, the sheath (31) is mounted on the hub (37) of a standard needle (21) that serves to connect the fine short needle (33) in flow relationship with the contents of the syringe (22). Following the injection of a minute quantity of anaesthetic subcutaneously through the fine short needle (33) to anaesthetise the injection site, the sheath (31) is detached from the hub (37) of the standard needle (21), that is then available for use in injecting a larger volume of anaesthetic, but with less pain than if the standard needle (21) were used without the initial subdermal injection.

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PAINLESS NEEDLE AND SHEATH ASSEMBLY

BACKGROUND ART

This invention relates to apparatus providing a means for the relatively painless injection of liquids into the body using standard hypodermic needles and syringes.

The penetration of the skin with a hypodermic needle is usually significantly painful. Also, the thicker the needle, the more pain is experienced during skin penetration. Conversely, the thinner and sharper the needle, the less painful skin penetration will be. However, it is necessary to make the needle from a relatively thick cannula because needles not only have to penetrate the skin, but must also travel to deeper tissues. If the needle is too thin, it will deflect on contacting ligament, muscle or bone, possibly deflecting away from its target area, unbeknown to the operator. Therefore, a needle used to penetrate into the body must be of a minimum thickness to prevent deflection and breakage. Therefore, we presently cannot use a thinner needle to minimise the pain of skin penetration because that same needle must be used to deliver solution to deeper tissues and therefore must be relatively thick.

The prior art does not provide the possibility of making an initial skin penetration painlessly. This is because the prior art is simply a standard hypodermic needle, and the standard hypodermic needle must be relatively thick. The invention solves the problem of the prior art being a relatively thick standard hypodermic needle.

Although the prior art is a relatively thick needle, the desire of manufacturers and operators of hypodermic needles has been to minimise skin penetration pain.

Much study and investigation has gone into minimising penetration pain.

Techniques of penetration pain minimisation, which are currently used and would comprise the prior art to this invention are the following:

1) Topical anaesthetic placed on the skin to numb the superficial nerve endings. (Reference - All articles on pain minimisation except Dr. Kelner (#3), who recommends attempts to scratch the skin surface with the needle point and allow anaesthetic to soak into the skin.)

2) Pressure anaesthesia where pressure is applied to the skin to cut off the blood supply to the nerves, and thus leave the nerves anoxic and less able to function. (Reference #1 and #2)

3) The application of a counter irritant, where the operator touches or squeezes the person's skin to fire nerve signals which confuse the nerve signals received by the brain, thus dulling the perception of pain to the individual. (Reference #3, #4 and #6)

4) Hypnosis to change the mental perception of pain. (Reference #2)

5) Increasing the sharpness of the needle point so that the needle will slide into the tissue with the least pressure, and therefore the least contact with subdermal nerve endings. (Reference #7)

6) Reducing the size or thickness of the needle used to penetrate the tissue. There has been much comparison on needle gauge and the associated differences of pain with a thinner and/or thicker needle. There is much controversy within the profession as to whether a thinner needle hurts less. The minimum thickness of a

needle is determined by deflection resistance and ability to aspirate. (Reference #8, #9 and #10)

Dr.'s Fuller, Menke, and Meyers, in their study of the Perception of Pain to Three Different Intraoral Penetrations of Needles concludes, "There are no significant differences in perception of pain produced by penetrations of 25, 27, and 30 gauge needles in the retro molar fossa." (Reference #12)

Dr.'s Mollen, Ficara, and Provant in their article, Needles - 25 gauge versus 27 gauge - can patients really tell?, concluded their study this way, "Statistical analysis showed no difference between the 25 gauge needle and the 27 gauge needle relative to the pain of needle insertion for inferior alveolar block anaesthesia. (Reference #13)

Dr. Risto Lehtinen from the University of Turku, Finland, in his article, (#14), Penetration of 27 and 30 Gauge Dental Needles, said in his discussion, "None of the subjects felt the 27 gauge needle more painful than the 30 gauge needle." (Reference #14)

Dr. Hamburg in his study, Preliminary Study Of Patient Reaction to Needle Gauge, concluded, "The gauge of the needle and pain reaction to the injection were not dependant variables." (Reference #11)

The four above quotes say that there is a pain experience with injections, and that gauge makes no difference in that pain experience. However, the following quotes from the literature discuss the opposite. These quotes say that the use of a finer gauge needle is helpful in minimising the trauma and pain on injection, and other quotes indicate that injections do not have to have pain associated with them at all.

Dr. Malamed said, "...I have found that the initial penetration of mucous membrane can usually be carried out without the patient even being aware of it." (Reference #1)

Dr. Kelmer wrote, "The entire procedure (meaning the injection) can be accomplished without the patient even being aware that he has had an injection." (Reference #3)

Rather than a comparison of the pain difference of different gauged needles, these above 2 quotes speak of no pain experienced at all.

Dr.'s Bedi, King, and Brook wrote, "Discomfort caused by the needle passing through the soft tissues can be reduced by replacing the rather long 27 gauge needle by the shorter, smaller bore number 30 gauge ... ", and also wrote, "Mandibular nerve block has a number of associated problems such as the size of the needle ... " (Reference #5)

Dr. Wolff wrote in his article, Technique/Atramatic Injection of Local Anaesthetics, "The patient is less likely to flinch during needle insertion if it is atramatic, and the 30 gauge needles are much kinder to tissue than the larger gauges." (Reference #4)

Dr. Morse, D.D.S. wrote together with Dr. Cohen, a Ph.D. Psychologist, the following, "The use of a fine bore disposable needle along with the application of pressure to the injection site can result in relatively painless injections." (Reference #2)

Dr.'s Coley and Robison wrote, "Some clinicians believe that the best way to reduce the discomfort of the injection is to use a smaller gauge needle." (Reference #6)

Even Dr.'s Mollen, Ficara and Provant, who's article argues against a difference in the pain experience of penetration with 25 and 27 gauge needles, mentions that, "The modern trend has been towards finer gauge needles." (Reference #13)

The literature obviously expresses 2 different views. How is it possible that the views of less trauma from finer needles from many colleges are not born out

by the studies. The reason is simple. The studies do not attempt to use techniques which minimise pain in the first place.

The first 3 mentioned studies (Ref. 12, 13, 14 and 11) did not demonstrate a difference between the pain of a 30 gauge to a 25 gauge needle. However, these studies directly thrust the compared needles directly into the nerve endings. The other authors (Ref. 5, 4, 2 and 6) mentioned after that believe, despite the claims of the above studies, that pain can be minimised by needle gauge.

Although the controversy exists within the dental profession as to whether thinner needles cause less pain or not, it has been decided by this inventor that needle gauge does make a difference in pain perception, particularly in the palate. From experimenting on himself and penetrating the roof of his mouth with both a 30 gauge and a smaller 33 gauge needle, he discovered a significant difference in pain perception. However, the inventor also found from penetration of his own looser oral skin, that there is not much pain difference when penetrating loose skin with different gauged needles. It is assumed by the inventor that pain receptors signal a pain difference in accommodating a larger gauge needle in thick fibrous skin, but the accommodation of a thicker needle in loose tissue is not noticed by the nerve endings. Thus, this inventor concluded that penetration pain of fibrous thick tissue can be reduced by using a fine gauge needle. This information is not generally known by the profession, as there are no studies of compared penetrations into the palate. This knowledge is from the inventor's own research, and from this research the inventor found the need within the profession for a small thin needle.

Manufacturers also attempt to make needles as small as possible. Manufacturers make needles just large enough to provide strength to resist deflection and breakage, and large enough to provide a large enough bore to aspirate through. Aspiration is the drawing back of blood in case the needle enters a blood vessel, and for this, the needle must be relatively thick.

Manufacturers make their needles as thin as possible and as sharp as possible to minimise pain. This is the previous art to minimising the pain of hypodermic needles.

One might think that with all this effort and study and desire by the manufacturers to make the needle of as small a gauge as possible, why did no one think to place a fine thin needle on top of a standard needle to first deposit anaesthetic below the skin, and then to use the standard hypodermic needle, which by necessity is somewhat thick? The answer is because studies show no difference in pain perception of small differences in gauge. It is only in the palate that there is a difference in pain perception, and this was not previously studied.

Study of the anatomy has always been a part of the study of injections. The inventor participated in another study where he received injections, and noticed a specific, significant searing pain at a specific depth of penetration during the mandibular block injection. After studying the anatomy, he decided that this pain was caused by the penetration of the buccinator muscle.

The buccinator muscle lies below the skin in the retro molar area. The depth of the muscle under the skin surface in children may be 2-3 mm, and in large adults, may be as much as 10 mm.

Learning this, the inventor realised that a fine needle could be used to penetrate the skin in the retro molar area relatively painlessly and could be used to deliver anaesthetic against the buccinator muscle. After a period of about 30 seconds, the buccinator muscle would be anaesthetised. Then the dentist could penetrate through the buccinator to the mandibular nerve completely painlessly.

Understanding this, the inventor devised a fine short needle which can be secured to the standard hypodermic needle that is used for the mandibular block, so that the fine thin needle can be used first to penetrate the skin painlessly, then deposit a few drops of anaesthetic to anaesthetise the skin and then travel further to the buccinator and anaesthetise the buccinator. The fine thin needle is then

withdrawn from the skin and removed from the standard hypodermic needle mandibular needle, and then this standard needle is used to penetrate the skin and the buccinator painlessly, to anaesthetise the mandibular nerve painlessly.

The Background shows much desire and study of those skilled in the art of minimising the penetration pain of hypodermic needles. The background shows that such study has resulted in the development of detain techniques to minimise pain such a topical anaesthetics, pressure anaesthesia, counter irritant anaesthesia, hypnosis and sharper needles. However, the background also shows that there is a controversy within the profession whether or not reducing needle gauge is detectable to the patient as causing less pain. Therefore, although retrospectively the invention may appear obvious to those skilled in the art, it was not obvious because its actual value was not established. In other words, it was not obvious because it was not known if a slightly thinner gauge made any difference. It was only be experiencing the needle penetrations himself that the inventor believes that a fine gauge needle does cause less pain when penetrating fibrous tissue. Therefore, it was from this personal research and new knowledge that the invented needle assembly was developed. The background also goes on to show that a particular injection, the mandibular block, is a particularly painful injection, and that the inventor discovered, again through his own research, that the mandibular block could be delivered painlessly if the buccinator was anaesthetised.

Thus, in accordance with his own research and new knowledge which he has discovered, the inventor devised an invention whereby a small thin needle could be used to fit over the standard hypodermic needle. This new needle was to have the use of penetrating fibrous tissue less painfully, and to penetrate the skin over the buccinator muscle painlessly, and to deposit anaesthetic beside the buccinator so that penetration of the buccinator during the mandibular block would be painless.

Thus, the invention has tremendous value in the dental profession.

The inventor has also designed the invention for similar uses in medicine.

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Reference #4 Wolff, J., D.D.S.: Technic - atraumatic injection of local anaesthetics. Dental Survey 46, pp 37-43. January 1970.

Reference #5 Bedi, R., King, N.M., Brook, A.H.: Local Anaesthesia for Children. Dental Update. June 1984.

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Reference #13 Mollen, A.J., D.D.S., Ficara, A.J., D.D.S., M.S., Provant, D.R., D.D.S., M.S.: Needles - 25 gauge versus 27 gauge - can patients really tell? Gen. Dent. 29, pp 417-418. 1981.

Reference #14 Lehtinen, R.: Penetration of 27- and 30-gauge dental needles. Int. J. Oral Surg. 12: 444-445. 1983.

DISCLOSURE OF THE INVENTION

This invention provides a means whereby the site of needle penetration or other minor medical procedure may be first anaesthetised by using a very fine needle for the subdermal injection of a minute quantity of an anaesthetic.

The invention provides a fine and short needle mounted on a sheath that is slipped over the prior art standard hypodermic needle. The new fine short needle is used to penetrate the tissue relatively painlessly. Anaesthetic is then injected through the fine short needle to just under the skin. Then the fine short needle and its sheath are removed from the standard hypodermic needle. The standard hypodermic needle is then used to penetrate the skin painlessly, and to slowly deposit the desired solution.

In accordance with one embodiment of my invention, a needle for use with a standard hypodermic needle in injecting small quantities of anaesthetic subdermally comprises a sheath having axially opposed forward and rearward ends and a bore extending between the ends. A barrier wall, made of a penetrable rubbery like septum is disposed within the bore of the sheath, creating a sealed flow area at the forward end of the sheath. A fine short needle is sealed at the forward end of the sheath, in flow communication with the bore within the sheath.

A movable wall that could be a flexible diaphragm is situated within the bore of the sheath, within the sealed flow area between the rubbery septum and the sealed fine short needle. The movable wall divides the sealed flow area into a forward and rearward compartment. The movable wall will move when there are differences in pressure within the forward and rearward compartments. The forward compartment is loaded at the factory with anaesthetic and the anaesthetic may be held and protected within the forward compartment with a cap over the fine short needle. The rearward end of the sheath fits snugly onto the hub of the standard hypodermic needle. The rearward end is also designed to stop on the

hub and situate the point of the standard hypodermic needle in the rearward compartment.

In another embodiment, the rearward end of the support member fits snugly on the shaft of the standard hypodermic needle. In this embodiment, the rubbery septum is not needed.

The fine short needle is ideally as fine as possible, but for human use may be as large as a 30 gauge standard hypodermic needle . The fine short needle ideally ranges in length from as short as is needed to just penetrate the first layer of skin that would be less than 1 mm to a maximum length needed to reach a particular structure beneath the skin. It should be noted that the fine short needle may be part of the structure of the sheath itself and made from the same material as the sheath, if manufacturers can create a sheath from a sufficiently hard material to make a sharpened point. The fine short needle is relatively fine and or short when compared to the standard hypodermic needle it is intended to be used with.

In another embodiment, the support member is used with a standard hypodermic needle that is attached to a syringe that carries anaesthetic. In this embodiment, the movable wall within the sealed flow area is not needed.

Not only will the narrowing stop and position the point of the standard hypodermic needle point, but the narrowing can be shaped so as to fit to and partially obstruct the bevelled opening of the lumen of the standard hypodermic needle, thus reducing the flow and pressure within the sealed flow area.

The foregoing objects and aspects of the invention, together with other objects, aspects and advantages thereof, will be more apparent from a consideration of the following descriptions taken in conjunction with the drawings annexed hereto.

Figure 1 shows the invention that uses the fine short needle and sheath over a standard hypodermic needle that will inject a solution that is not an anaesthetic.

It is desired that the skin be numbed with a fine needle previous to the delivery of any solution with the hypodermic needle. A fine short needle 43 is attached and sealed in a flow relationship with the bore 44 of a narrow sheath 41. At the forward end of the sheath 41 there is a septum 49 made of a thick rubber like material that creates a sealed flow area within the forward end portion of the sheath 41. In this sealed flow area there is a movable wall 42 that could be an elastic diaphragm. The movable wall divides the sealed flow area into two compartments, a rearward compartment 54 and a forward compartment 55. The narrow sheath 41 extends to an attachment at the rearward end of the sheath 41 that friction fits or latch grips the hub 47 of the standard hypodermic needle 21 it was designed to be used with. When the sheath 41 is slipped over the standard hypodermic needle 21, the attachment 46 of the sheath will seat to a stop 32 on the hub 47, such that the standard hypodermic needle 21 will penetrate the septum 49 and enter into, but will not extend past, the rearward compartment 54 between the septum and the movable wall.

The forward compartment 55 between the movable wall and the tip of the sheath is loaded at the factory with 2 or 3 millilitres of anaesthetic. The cap 96 holds the anaesthetic in compartment 55 when seated over the fine short needle. Syringe 22 can inject solution through the standard hypodermic needle into the rear compartment 54 with pressure to move the movable wall 42 and expel the contents of anaesthetic in compartment 55.

The anaesthetic in compartment 55 can be deposited using the fine short needle 43 just under the skin to numb the chosen area. The sheath 41 can now be slipped off the standard hypodermic needle 21. The standard hypodermic needle 21 can now itself penetrate the skin in the numbed area painlessly and can continue to the target area and deposit the necessary solution.

Figure 2 shows an embodiment of the invention that does not need to be made to fit to the hub of any specific manufacture of a standard hypodermic

needle, but can instead fit to the standard hypodermic needle itself. Figure 2 shows the fine short needle 17 sealed to the forward end portion of the sheath 11 where the bore 14 at the rearward end of the sheath 11 fits snugly around the circumference of the standard hypodermic needle 21. The sealed flow area within the bore 14 of the sheath extends from the tip of the snugly fitted standard hypodermic needle 21 to the sealed fine short needle. No rubbery septum is needed when the sheath snugly fits the standard hypodermic needle, providing its own sealing. A movable wall 12 is situated within the sealed flow area, dividing the sealed flow area into two compartments, a forward compartment 65 and a rearward compartment 64.

Since the rearward end portion in this embodiment does not seat on the hub of the standard hypodermic needle 21, there is a stop 52 extending out from the inner wall of the bore 14 in the rearward compartment 64 to situate the standard hypodermic needle 21 within the rearward compartment, when the sheath is slipped over the standard hypodermic needle 21.

The forward compartment 65 is loaded with an anaesthetic and a cap 96 holds and protects the anaesthetic within the compartment. The use of the embodiment of the invention shown in Figure 2 is the same as the use of the first embodiment shown in Figure 1.

In Figure 3, a fine short needle 33 is attached to the end of a narrow sheath 31 that has bore 34. The fine short needle 33 is in a sealed flow communication with the bore 34 of the sheath. Near the forward end of the sheath 31, there is a septum 39 that is made of a thick rubbery type of material. The septum 39 creates a sealed flow area 35 at the forward end of the sheath 31 and the fine short needle 33 is in flow communication with the sealed flow area 35. The sheath 31 extends rearwardly from the fine short needle 33 and ends with an attachment 36 that can friction fit or latch grip with a bayonet mount or a snap on and off function to the hub 37 of a standard hypodermic needle 21. The length of

the sheath 31 and the length and shape of the attachment 36 are made specifically for each type of hypodermic needle it is to be used with. The length of the sheath 31 and the shape of the attachment 36 are made in a manor so that when the attachment 36 of the sheath friction or latch grips the hub 37 of the needle, it will come to a stop 32 on the hub 37 of the standard hypodermic needle so that the needle tip will extend up inside the sheath and penetrate the septum 39 to enter into and be stopped in the sealed flow area 35. With the sheath 31 stopped in this position, the operator can now inject through the standard hypodermic needle 21 into the sealed flow area 35 and then through the fine short needle 33.

After the application of a topical anaesthetic, the fine short needle 33, that is mounted on a standard hypodermic needle 21 and syringe 22 that contains anaesthetic, can then be used to slip under the skin ever so slightly to slowly deposit a few millilitres of anaesthetic solution. This anaesthetic will numb the skin surface better than any topical anaesthetic can. The sheath 31 and fine short needle 33 are then pulled off the hypodermic needle 21 and the hypodermic needle 21 can be used to now penetrate the anaesthetised skin painlessly and, proceed through the tissue to the target area and slowly deposit the anaesthetic solution.

Figure 4 shows the isolated enlargement of a very simplified sheath and fine needle where the sheath fits snugly to the standard hypodermic needle as in Figure 2. The sheath structure is indicated by number 11. Number 14 points to the bore and number 19 points to the narrowing of the bore to seal the fine short needle. The narrowing of the bore provides the stop for the standard hypodermic needle shown by number 21. The stop situates the point of the standard hypodermic needle in the sealed flow area 35 and protects both the rearward end of the fine needle and the point of the standard needle.

Figure 5 is the same as Figure 4 except that the narrowing of the bore 19 takes place largely on one side of the bore, so that the inner narrowing wall of the

bore fits to the bevel of the standard hypodermic needle. this blockage reduces the flow from the standard hypodermic needle, and directs the hydraulic pressures outwardly towards the walls of the sheath and reduces the axial hydraulic pressures that could tend to dislodge the sheath from the standard hypodermic needle.

The use of the sheath and fine needle shown in Figures 4 and 5 are the same as the use described for the embodiments shown in Figure 3.

DRAWINGS

Figure 1 shows a cross-section of a sheath and fine needle with two compartments at the forward end portion of the sheath, seated over the standard hypodermic needle, with the standard hypodermic needle placed into the rearward compartment where it can inject solution to push the moveable wall and expel the contents of the forward compartment. The cap 96 protects the fine short needle and its contents of anaesthetic.

Figure 2 shows a cross-section of a sheath and fine needle that is friction fitted over the shaft of the standard hypodermic needle. An enlargement of the internal forward section of the bore shows the moulded in stop for the standard hypodermic needle tip. The cap 96 protects the fine short needle.

Figure 3 shows the sheath and fine needle in Figure 1 seated in place over the standard hypodermic needle, ready for use. This sheath, however, does not have the movable wall 42 and so has only the one sealed flow area. The sheath and fine short assembly is to be filled with anaesthetic from a standard syringe through a standard hypodermic needle.

Figure 4 shows the enlargement of the sealed flow area of a simplified sheath and fine needle where the sheath fits snugly on the shaft of the standard hypodermic needle as in Figure 2. There is no movable wall. The stop is formed by the narrowing of the bore to seal the fine short needle.

Figure 5 shows the enlargement of the sealed flow area of a simplified sheath and fine needle as in Figure 4 where the narrowing of the bore takes place largely on one side of the bore so that the inner surface of the narrowing portion

of the bore is the mate of the bevel of the point of the standard hypodermic needle so that narrowing portion of the bore partially blocks the opening of the lumen of the standard hypodermic needle.

I CLAIM:

1. A needle assembly to be mounted over a standard hypodermic needle where said needle assembly comprises;

- a slim sheath having axially opposed forward and rearward end portions and defining a bore therein: and

- a fine short needle fixed to the forward end portion in flow relationship with the bore: and

- a sealed flow area at the forward end portion of the sheath so that solution injected into the sealed flow area will flow out the small thin needle and not back out along the rearward end portion of the sheath: and

- a rearward end portion shaped to attach the assembly to the standard needle: and

- a moveable wall that is placed within the sealed flow area of the forward end portion of the sheath, thus dividing the sealed flow area into 2 compartments, a forward compartment and a rearward compartment so that the movable wall will move as forced by differences in pressure within the 2 compartments: and

- a stopping feature within the structure of the sheath where the stop in the sheath positions the standard hypodermic needle point in the sealed flow area and protects the septum, movable wall, fine needle and point of the standard hypodermic needle.

2. A needle assembly as in Claim 1 where:

- the rearward end portion is shaped to attach to the hub of a standard needle: and

- the rearward end portion is shaped to fit on the standard hub so that it positions the point of the standard hypodermic within the rearward compartment.

3. A needle assembly as in Claim 1 where:

- the rearward end portion fits snugly on the shaft of the standard needle: and

- there is a moulded extension on the inner wall of the sheath that positions the point of the standard hypodermic needle within the rearward compartment.

4. A needle assembly as in Claim 1 where:

- there is no movable wall in the sealed flow area: and

- the rearward end portion is shaped to attach to the hub of a standard needle: and

- the rearward end portion is shaped to fit on the standard hub so that it positions the point of the standard hypodermic within the sealed flow area.

5. A needle assembly as in Claim 1 and 3 where:

- the rearward end portion is shaped to fit snugly on the shaft of the standard hypodermic needle: and

- there is no movable wall within the sealed flow area: and

- the point of the standard hypodermic needle is stopped in the sealed flow area by the narrowing of the bore of the sheath as the bore narrows to seal the fine short needle.

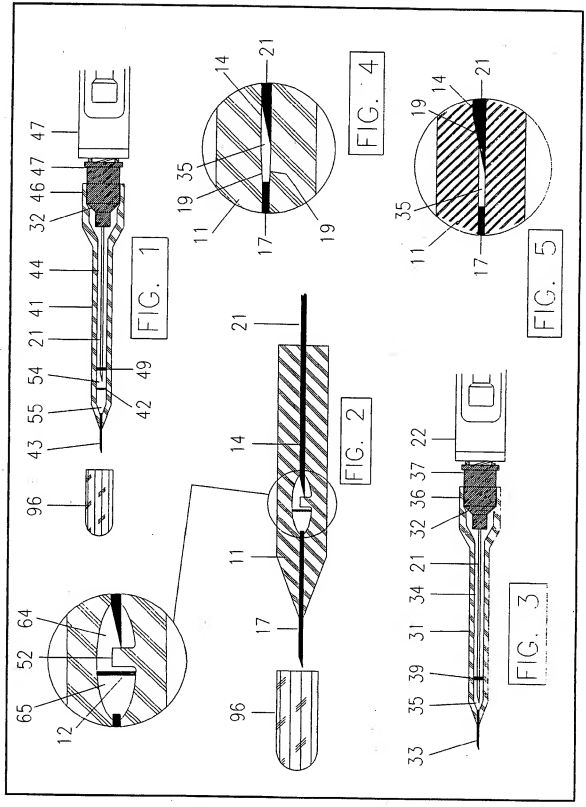
6. A needle assembly as in Claim 1, 3 and 5 where:

- the rearward end portion is shaped to fit snugly on the shaft of the standard hypodermic needle: and

- there is no movable wall within the sealed flow area: and

- the point of the standard hypodermic needle is stopped in the sealed flow area by the narrowing of the bore of the sheath as the bore narrows to seal the fine short needle: and

- the opening of the lumen of the standard hypodermic needle is partially blocked by the narrowing of the bore which provides the stop to the standard hypodermic needle.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47 46 32
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41 21
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96
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FIG. 1
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FIG. 4
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FIG. 5
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FIG. 2
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FIG. 3
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